

1       INTR-A-OPERATIVE PROCEDURE FOR POST-OPERATIVE PAIN CONTROL

2

3       FIELD OF THE INVENTION

4           This invention relates to a procedure for essentially  
5       eliminating post-operative pain concomitant with surgical  
6       procedures; particularly to methods for essentially  
7       eliminating pain associated with the implant of prosthetic  
8       devices to repair and/or replace natural joints; and most  
9       particularly to methods for essentially eliminating pain  
10      associated with hip and knee replacements.

11

12      BACKGROUND OF THE INVENTION

13           Natural joints often become damaged either as a result  
14       of traumatic injury, as a result of some disease process,  
15       e.g. osteoarthritis, or as a side effect of various  
16       pharmacological treatments, e.g. corticosteroid therapy.  
17       This often leads to muscular atrophy, immobility, reduced  
18       load capacity, chronic pain and a general reduction in the  
19       patient's quality of life.

20           The use of prosthetic devices to replace damaged natural  
21       joints, in whole or in part, has become widespread, as  
22       medical and technological advances have joined to provide  
23       improved materials and designs for prosthetic devices and  
24       innovative techniques for their implantation. Modern

1 prosthetic devices are capable of providing a repaired joint  
2 of maximum efficiency; furthermore current techniques for  
3 implanting such prosthetic devices require only minimal  
4 intrusion into the body of the recipient. However, patients  
5 are frequently reluctant to undergo these types of surgery  
6 due to the extreme post-operative pain, lengthy  
7 rehabilitation periods, and possibility of post-operative  
8 complications, such as blood clots, infection, and the like.

9 While post surgical pain relief is necessary to enable  
10 patients to become ambulatory as quickly as possible and to  
11 enable the initiation of physiotherapy, physicians must  
12 nevertheless weigh the magnitude of pain relief achieved  
13 against the possibility of adverse reactions, functional  
14 outcomes and length of hospital stay .

15 Such pain modalities as epidural analgesia, while  
16 providing good pain relief immediately after surgery, have  
17 certain drawbacks, such as delaying the start of blood  
18 thinners, which may be necessary to prevent life-threatening  
19 blood clot formation, due to the risk of epidural hematoma.  
20 Systemic analgesia, e.g. oral or intravenous use of various  
21 analgesics and narcotic agents also have inherent drawbacks  
22 such as nausea and vomiting, depression of breathing, urinary  
23 retention, and the like.

1       Thus, there is a longfelt need for a method of  
2       eliminating post-operative pain while avoiding the  
3       complications of commonly used analgesic modalities.

4       In order to encourage patients to become more amenable  
5       to joint replacement surgery, orthopaedic researchers have  
6       worked diligently to improve post-operative pain management.

7       Meissner *et al.* (Anesthesiology Abstracts of Scientific  
8       Papers Annual Meeting, abstract number 950, 2000) describe  
9       prophylaxis of post-operative pain in hip replacement surgery  
10      using multimodal intra-operative analgesics. The multi-modes  
11      of Meissner *et al.* include the use of spinal anesthesia with  
12      bupivacaine, local anesthetic skin infiltration,  
13      intramuscular injection of 1mg/kg diclofenac and intrathecal  
14      0.001mg/kg morphine administered together.

15      Verbeeck *et al.* (Anesthesiology Abstracts of Scientific  
16      Papers Annual Meeting, abstract number A-965, 2001) describe  
17      a protocol for peripheral nerve block after total hip  
18      replacement using a continuous infusion of ropivacaine.

19      Viscusi *et al.* (Anesthesiology Abstracts of Scientific  
20      Papers Annual Meeting, abstract number A-830, 2001) describe  
21      a protocol for pain management after total joint replacement  
22      in the lower extremities using injectable acetaminophen.

23      Singelyn *et al.* (Anesthesia and Analgesia 92(2):455-459  
24      2001) disclose a study in which methods for extended femoral

1 nerve sheath block after total hip replacement were compared.  
2 All patients in the study received 0.125% bupivacaine with  
3 clonidine 1μg/ml and sufentanil 0.1 1μg/ml administered via  
4 catheter continuously or patient-controlled.

5 Eggers et al. (British Journal of Anaesthesia 83(6):876-  
6 881 1999) disclose a study wherein the effect of oral and  
7 intravenous tenoxicam on postoperative pain after total knee  
8 replacement was evaluated. Tenoxicam was administered to two  
9 groups of patients, either before (40mg orally) or after (40  
10 mg intravenous) surgery, then 24 hours after surgery (40 mg  
11 intravenous) and at the end of each day for an 8 day period  
12 (20 mg orally). A third group of patients received a placebo  
13 at all times.

14 Martini et al. (Aktuelle Rheumatologie 22(2):69-74 1997)  
15 discuss whether pre-operative physiotherapy prior to total  
16 hip replacement in osteoarthritis of the hip joint improves  
17 post-operative pain management.

18 Gehling et al. (Anaesthesist 52:204-209 2003) disclose a  
19 study wherein the effect of clonidine on spinal morphine  
20 analgesia after major orthopaedic surgery was evaluated.

21 Adams et al. (European Journal of Anaesthesiology  
22 19:658-665 2002) disclose a study wherein the effect of  
23 endocrine stress on post-operative pain management in  
24 orthopaedic patients was evaluated.

1 Rasmussen et al. (American Journal of Orthopaedics  
2 31:336-343 2002) disclose a study wherein the effects of  
3 parecoxib sodium, morphine and ketorolac on post-operative  
4 pain management in total knee replacement were compared.

5 Mallory et al. (Journal of Arthroplasty 17:4 (Supp 1):  
6 129-133 2002) disclose a study wherein the effect of pre-  
7 operative treatment (2 weeks prior) with cyclooxygenase-2-  
8 inhibiting-anti-inflammatory medication on post-operative  
9 pain management after joint replacement surgery was  
10 evaluated.

11 Bogoch et al. (Journal of Arthroplasty 17:398-401 2002)  
12 disclose a study wherein the effect of lumbar paravertebral  
13 nerve block in addition to patient-controlled analgesia on  
14 post-operative pain management after total hip and knee  
15 arthroplasty was evaluated.

16 Camu et al. (American Journal Therapy pages 43-51,  
17 2002) disclose a study wherein the effect of valdecoxib on  
18 morphine consumption and post-operative pain after hip  
19 arthroplasty was evaluated. Valdecoxib is highly selective  
20 cyclooxygenase COX-2 specific inhibitor which was  
21 administered to patients pre and post-operatively.

22 Horlocker et al. (Reg Anesthesia Pain Med 27:105-108  
23 2002) disclose a study wherein the effect of continuous  
24 lumber plexus block in addition to acetaminophen and

1       ketorolac on post-operative pain after knee replacement was  
2       evaluated.

3           Kampe *et al.* (*Anaesthesia* 56(12):1189-1193 2001)  
4       disclose a study wherein the effect of an epidural infusion  
5       of ropivacaine and sufentanil on post-operative pain after  
6       hip replacement was compared with the effect of patient-  
7       controlled analgesia using piritramide on post-operative pain  
8       after hip replacement.

9           Chelly *et al.* (*Journal of Arthroplasty* 16:436-445 2001)  
10      disclose a study wherein the effect of continuous femoral  
11      infusion (CFI) on post-operative pain after knee replacement  
12      was evaluated. CFI was compared with patient-controlled  
13      morphine and epidural analgesia.

14          Pico *et al.* (*Canadian Journal of Anesthesiology* 47:309-  
15      314 2000) disclose a study wherein the effect of peroperative  
16      morphine on post-operative pain after hip arthroplasty was  
17      evaluated. In the experimental peroperative group, patients  
18      received titrated morphine beginning at the end of surgery.

19          Kopacz *et al.* (*Anesth Analg* 89:1497-1503 1999) disclose  
20      a study wherein the effects of levobupivacaine 0.125%,  
21      fentanyl 4mg/ml and their combinations on post-operative pain  
22      after major orthopedic surgery were compared. The analgesics  
23      were administered to the patients by patient-controlled  
24      epidural analgesia. All of the patients involved in this

1 study received 20ml of 0.75% levobupivacaine intra-  
2 operatively.

3 Wulf et al. (Anesth Analg 89:11-116 1999) disclose a  
4 study wherein the effect of epidural anesthesia and analgesia  
5 (ropivacaine) on post-operative pain after hip replacement  
6 was compared to the effect of general anesthesia  
7 (isoflurane/N2O/fentanyl) and patient-controlled morphine  
8 (intravenous) on post-operative pain after hip replacement.

9 Mauerhan et al. (Journal of Arthroplasty 12:546-552  
10 1997) disclose a study wherein the effect of intra-articular  
11 morphine on post-operative pain after knee replacement was  
12 compared with the effect of intra-articular bupivacaine on  
13 post-operative pain after knee replacement. Morphine and  
14 bupivacaine in combination was also tested. All injections  
15 were given to the patients immediately after surgery.  
16 Additionally, patients involved in this study used patient-  
17 controlled morphine (intravenous) post-operatively.

18 Cazeneuve et al. (Rev Chir Orthop Reparatrice Appar Mot  
19 82:705-708 1996) disclose a study wherein the effect of  
20 combined epidural and spinal anesthesia on post-operative  
21 pain after prosthetic surgery of lower limbs was evaluated.  
22 All patients involved in this study also received daily  
23 morphine injections and intravenous paracetamol.

1 Wong et al. (Canadian Journal of Anesthesia 44:31-37  
2 1997) disclose a study wherein the effect of pre-operative  
3 analgesia with ketamine, morphine and epidural lidocaine on  
4 post-operative pain after knee replacement was evaluated.

5 Colwell et al. (J Bone Joint Surg Am 77:726-733 1995)  
6 disclose a study wherein the effect of patient-controlled  
7 analgesia (narcotic) on post-operative pain after an  
8 orthopaedic procedure was compared to the effect of  
9 intramuscular injections of analgesics (narcotic) on post-  
10 operative pain after an orthopaedic procedure.

11 Striebel et al. (Anasthesiol Intensivmed Notfallmed  
12 Schmerzther 28:168-173 1993) disclose a study wherein the  
13 effect of a continuous 3-in-1 blockade (using bupivacaine) on  
14 post-operative pain after hip replacement was evaluated. All  
15 patients involved in this study also used patient-controlled  
16 meperidine (intravenous).

17 Moote, C. (Drugs 44 Suppl 5:14-30 1992) discloses that  
18 nonsteroidal anti-inflammatory drugs (NSAIDS) can be used in  
19 combination with conventional treatments to improve post-  
20 operative pain control after hip arthroplasty.

21 White, P.F. (Clinical Journal of Pain, pages 297-300  
22 1990) discloses a study wherein patient-controlled opioid  
23 analgesics were delivered either intravenously or

1 subcutaneously after major orthopedic surgery and the effects  
2 compared.

3 Walker et al. (Journal of Arthroplasty, pages 151-156  
4 1991) disclose a study wherein the effects of post-operative  
5 use of continuous passive motion, transcutaneous electrical  
6 nerve stimulation, and continuous cooling pad on post-  
7 operative pain after knee arthroplasty were evaluated.

8 Serpell et al. (British Journal of Anesthesiology  
9 63:354-356 1989) disclose a study wherein the effect of  
10 piroxicam on post-operative pain after hip replacement was  
11 evaluated. All of the patients included in this study also  
12 used patient-controlled morphine.

13 European Patent 00754064/EP B1, May 28, 2003, assigned to  
14 Atrix Laboratories, Inc., discloses a surgically implantable  
15 device (for use with human or animal tissue) in combination  
16 with an adjunctive polymer system. Analgesics and anesthetics  
17 may also be included within the adjunctive polymer system.

18 US Patent 6,559,119, May 6, 2003, discloses a surgically  
19 implantable biomedical device having a supplemental tissue  
20 sealant composition. Analgesics and anesthetics may also be  
21 included within the tissue sealant composition.

22 It is noted that practically all of the methods of pain  
23 control known and practiced in the art to date involve the  
24 use of multiple agents and/or multiple protocols to achieve

1 some level of success in pain management. The vast majority  
2 of these pain control methods are applied post-operatively,  
3 with a small percent applied pre-operatively and an even  
4 smaller percent applied intra-operatively. What is lacking in  
5 the art is a single method that can significantly reduce or  
6 eliminate post-operative pain and thus additionally reduce  
7 the length of recovery and rehabilitation periods. The  
8 availability of surgery with minimal or no pain and a rapid  
9 recovery would likely encourage patients to seek the surgery  
10 they are in need of.

11

12 SUMMARY OF THE INVENTION

13 The instant invention provides an intra-operative method  
14 for essentially eliminating post-operative pain associated  
15 with and resulting from surgical procedures. Incorporation of  
16 this method into a standard surgical protocol results in an  
17 essentially pain free recovery for the patient undergoing the  
18 surgical protocol.

19 Practice of this method is illustrated herein in  
20 conjunction with orthopedic surgeries (partial and total  
21 joint replacements); however the method is contemplated for  
22 use in conjunction with any musculo-skeletal operation in any  
23 area of the body.

24 The method of the instant invention is carried out by  
25 intra-operative administration of multiple injections of a

1 medicated solution within and around the area of a surgical  
2 incision or wound. In its broadest context, the medicated  
3 solution comprises a mixture of an injectable anesthetic,  
4 epinephrine, sodium chloride and an injectable anti-  
5 inflammatory agent. The type of anesthetic and anti-  
6 inflammatory agent can be selected according to individual  
7 patient need. Anesthetics and anti-inflammatory agents are  
8 well-known in the art and one of ordinary skill in the art  
9 would be familiar with their applications. Any injectable  
10 anesthetic is contemplated for use in the instant invention,  
11 illustrative of which are bupivacaine, ropivacaine,  
12 dibucaine, procaine, chloropropone, prilocaine, mepivacaine,  
13 etidocaine, tetracaine, lidocaine, xylocaine, levobupivacaine  
14 and the like, as well as anesthetically active analogs,  
15 derivatives and mixtures thereof. A particularly preferred  
16 injectable anesthetic is CHIROCAINE® (levobupivacaine), the  
17 use of which is exemplified in the examples described herein.  
18 Any injectable steroidal or non-steroidal anti-inflammatory  
19 is contemplated for use in the instant invention, such as  
20 ketorolac tromethamine and propecatomol. A particularly  
21 preferred anti-inflammatory agent is TORADOL® (ketorolac  
22 tromethamine), the use of which is exemplified in the  
23 examples described herein. Stock medicated solutions for use  
24 in the method of the instant invention are prepared in doses  
25 in accordance with patient body weight wherein 160 pounds is

1 the baseline patient body weight. Typically, a medicated  
2 solution in a dose of about 60ml is prepared for patients  
3 weighing less than 160 pounds and a dose of about 80 ml is  
4 prepared for patients weighing 160 pounds or more. The dosage  
5 of medicated solution can also be prepared from baseline by  
6 increasing or decreasing the amounts of solution with every  
7 25 pound change in patient body weight. The complete dosage  
8 is administered to the patient by multiple injections wherein  
9 a single injection comprises approximately 5cc of the  
10 medicated solution. Although it is possible to utilize a  
11 variety of syringe types in carrying out the instant method,  
12 administration is preferably carried out via the use of a  
13 specifically designed needle, which is exemplified as an 18  
14 gauge spinal needle comprising a shaft having a blocked end  
15 and a plurality of circumferentially positioned apertures in  
16 the shaft just proximal to the blocked end of the shaft.

17 This method is exemplified herein through application in  
18 three types of orthopedic surgery, total hip replacement  
19 (THR), unicondylar knee replacement or "UNI-knee" surgery and  
20 total knee replacement (TNR). In THR, Figure 7, UNI-knee,  
21 Figure 8 and TKR, Figure 9 the method was highly efficacious.  
22 These patients had minimal or no pain; they required little  
23 or no additional agents and/or protocols for pain management  
24 and they did not spend any time in rehabilitation hospitals.

25 Accordingly, it is an objective of the instant invention

1 to provide an intra-operative method for essentially  
2 eliminating pain associated with and resulting from surgical  
3 procedures, said method comprising multiple intra-operative  
4 injections of a medicated solution.

5 It is a further objective of the instant invention to  
6 provide a method for essentially pain free orthopedic  
7 surgery.

8 It is yet another objective of the instant invention to  
9 provide a combination of ingredients useful for forming a  
10 medicated solution for use with the intra-operative method  
11 for controlling pain comprising an injectable anesthetic,  
12 epinephrine, sodium chloride and an injectable anti-  
13 inflammatory agent administered in amounts according to  
14 patient body weight.

15 It is a further objective of the instant invention to  
16 provide a needle specifically designed for use with the  
17 intra-operative method for controlling pain wherein the  
18 needle is a spinal needle, illustrated, albeit not limited to  
19 an 18 gauge spinal needle.

20 It is yet an additional objective of the instant  
21 invention to provide a needle of specific design for  
22 distribution of the medicated solution comprising a shaft  
23 having a blocked end and a plurality of circumferentially  
24 positioned apertures in the shaft just proximal to the  
25 blocked end of the shaft.

1        It is a still further objective of the instant invention  
2        to provide a kit comprising the components of the medicated  
3        solution, one or more suitable needles, which may include the  
4        specially designed needle herein disclosed, along with  
5        instructions for their use in carrying out the intra-  
6        operative pain elimination protocol.

7        Other objectives and advantages of the instant invention  
8        will become apparent from the following description taken in  
9        conjunction with the accompanying drawings wherein are forth,  
10      by way of illustration and example, certain embodiments of  
11      the instant invention. The drawings constitute a part of this  
12      specification and include exemplary embodiments of the  
13      present invention and illustrate various objects and features  
14      thereof.

15

16      BRIEF DESCRIPTION OF THE FIGURES

17      FIGURE 1 illustrates a needle contemplated for use with  
18      the method of the instant invention;

19      FIGURE 2 illustrates injection sites on posterior  
20      exposure of the hip;

21      FIGURE 3 illustrates injection sites on exposure of the  
22      knee;

23      FIGURE 4 illustrates injection sites used in knee  
24      surgery;

25      FIGURE 5 illustrates injection sites on exposure of the

1 knee;

2 FIGURE 6 illustrates injection sites used in UNI knee  
3 surgery;

4 FIGURE 7 shows a table of results obtained when using  
5 the method of the instant invention in total hip replacement  
6 surgery;

7 FIGURE 8 shows a table of results obtained when using  
8 the method of the instant invention in partial knee  
9 replacement surgery;

10 FIGURE 9 shows a table of results obtained when using  
11 the method of the instant invention in total knee replacement  
12 surgery.

13

#### 14 DEFINITIONS AND ABBREVIATIONS

15 The following list defines terms, phrases and  
16 abbreviations used throughout the instant specification.

17 Although the terms, phrases and abbreviations are listed in  
18 the singular tense the definitions are intended to encompass  
19 all grammatical forms.

20 As used herein, the abbreviation "THR" refers to a total  
21 hip replacement; an orthopedic surgical procedure wherein the  
22 joints of the hip which have been damaged by disease or  
23 trauma are replaced with prosthetic joints.

24 As used herein, the abbreviation "TKR" refers to a total

1       knee replacement; an orthopedic surgical procedure wherein  
2       the joints of the knee which have been damaged by disease or  
3       trauma are replaced with prosthetic joints.

4           As used herein, the abbreviation "UNI-knee" refers to a  
5       partial knee replacement; an orthopedic surgical procedure  
6       wherein the joints of the knee which have been partially  
7       damaged by disease or trauma are partially replaced with  
8       prosthetic joints. A "UNI-knee" does not require replacement  
9       of the entire knee joint and can also be referred to as a  
10      "UNI-compartmental", "UNI-lateral" or "UNI-condylar" knee  
11      replacement.

12          As used herein, the term "natural joint" refers to an  
13       organic, biological joint which is not a prosthetic device  
14       made by man.

15          As used herein with regard to the preparation of the  
16       medicated solution, the phrases "another suitable injectable  
17       anesthetic" and "another suitable anti-inflammatory agent"  
18       indicate that many different anesthetics and anti-  
19       inflammatory agents can be used with the medicated solution  
20       and are chosen according to what best suits an individual  
21       patient's needs.

22

23      DETAILED DESCRIPTION OF THE INVENTION

24          Surgery is frequently a necessary and life-saving

1 procedure useful in cases of both trauma and disease. Surgery  
2 can also be "elective" for improvement of quality of life in  
3 non-life threatening injuries and/or disease. Unfortunately,  
4 surgeries are often associated with extreme pain, possible  
5 complications, and prolonged rehabilitation. No individual  
6 looks forward to a painful experience, and thus patients are  
7 frequently reluctant to undergo elective surgical procedures.  
8 This scenario is especially true for orthopedic joint  
9 replacement surgery.

10 Natural joints often become damaged either as a result  
11 of traumatic injury, as a result of some disease process,  
12 e.g. osteoarthritis, or as a side effect of various  
13 pharmacological treatments, e.g. corticosteroid therapy.  
14 This often leads to muscular atrophy, immobility, reduced  
15 load capacity, chronic pain and a general reduction in the  
16 patient's quality of life. Prosthetic joints can ameliorate  
17 these symptoms and thus improve the quality of life for these  
18 patients. However, these patients often avoid these surgeries  
19 because of the extreme post-operative pain attributed to  
20 them. The instant invention provides a method that can  
21 significantly reduce or eliminate post-operative pain and  
22 thus additionally reduce the length of recovery and  
23 rehabilitation periods.

24 Generally, the method of the instant invention comprises

1       two basic steps; preparation of a medicated solution and  
2       intra-operative injection of this medicated solution, by an  
3       appropriately trained and certified clinician, to selected  
4       sites within the surgical field, e.g. at particular  
5       areas within the boundaries of the surgical procedure being  
6       performed.

7

8       PREPARATION OF THE MEDICATED SOLUTION

9           The total amount of medicated solution required per  
10      procedure is dependent on a patient's body weight. A body  
11      weight of 160 pounds (70 kilograms) is the baseline from  
12      which dosages are calculated. Usually, the total amount of  
13      medicated solution increases or decreases with each 25 pound  
14      change in patient body weight.

15           The medicated solution comprises a mixture of a suitable  
16      injectable anesthetic, illustrated by, but not limited to  
17      CHIROCAINE®, epinephrine, sodium chloride and a suitable  
18      anti-inflammatory agent illustrated by, but not limited to  
19      TORADOL®, and is prepared according to the following  
20      protocols:

21      PROTOCOL TO BE USED FOR PATIENTS WITH BODY WEIGHTS OF LESS  
22      THAN 160 POUNDS

23           1. Add 50 ml 0.5% CHIROCAINE® (or another suitable  
24      injectable anesthetic) to 0.5 ml epinephrine (1:1000) and

1 mix;

2       2. Dilute the mixture to 100 ml using preservative free

3 sodium chloride (NaCl); the concentration of CHIROCAINE®

4 should equal 0.25%;

5       3. Remove 20 ml of the mixture in syringe for

6 subcutaneous injection around the wound;

7       4. Discard 20 ml of the mixture;

8       5. Add 60 mg of TORADOL® (or another suitable injectable

9 anti-inflammatory agent) resulting with 60 ml of medicated

10 solution to be used in the injections.

11

12 PROTOCOL TO BE USED FOR PATIENTS WITH BODY WEIGHTS OF 160

13 POUNDS OR MORE

14       1. Add 50 ml 0.5% CHIROCAINE® (or another suitable

15 injectable anesthetic) to 0.5 ml epinephrine (1:1000) and

16 mix;

17       2. Dilute the mixture to 100 ml using preservative free

18 sodium chloride (NaCl); the concentration of CHIROCAINE®

19 should equal 0.25%;

20       3. Remove 20 ml of the mixture in syringe for

21 subcutaneous injection around the wound;

22       4. Add 60 mg of TORADOL® (or another suitable injectable

23 anti-inflammatory agent) resulting with 80 ml of medicated

24 solution to be used in the injections.

1       INTR-A-OPERATIVE INJECTION OF THE MEDICATED SOLUTION

2           In a contemplated embodiment of the invention,  
3   injections would be deliverable using a syringe for  
4   containing the medicated solution coupled to a hollow shaft  
5   or needle specifically designed for use with the method  
6   described herein.

7           With reference to Figure 1, the needle is illustrated as  
8   having a shaft 1 characterized as a hollow shaft having a  
9   proximal end and a distal end, wherein said medical solution  
10   flows from the syringe (not shown) within said shaft from  
11   said proximal end toward said distal end, which distal end is  
12   defined by a solid end 2 having a plurality of  
13   circumferentially positioned apertures 3 in said shaft for  
14   providing radially directed flow of the medicated solution  
15   about the entire circumference thereof. This design enables  
16   radially directed flow of the medicated solution about the  
17   entire circumference of the shaft, thus directing the flow  
18   around the surface of the prosthesis. This radial and  
19   circumferential flow path affords protection to the vascular  
20   and nerve structures, which could otherwise be traumatized or  
21   damaged by forceful pressure of the injected fluid. In a  
22   preferred, albeit non-limiting embodiment, the needle would  
23   be fabricated from an 18 gauge spinal needle.

24           The total volume of the dose of medicated solution is

1 delivered using multiple injections of approximately 5cc  
2 each. The term "approximately" as used herein, is intended to  
3 mean that the volume of a single injection is brought near or  
4 close to 5ccs; in amounts of solution either slightly greater  
5 or smaller than 5ccs.

6 With reference to Figures 2-6, illustrated therein are  
7 suggested sites (X) for administration of the medicated  
8 solution in accordance with the instant invention in both hip  
9 and knee joint replacements. Fig. 2 illustrates injection  
10 sites on posterior exposure of the hip; Fig. 3 illustrates  
11 injection sites on exposure of the knee; Fig. 4 illustrates  
12 injection sites used in UNI knee surgery; Fig. 5 illustrates  
13 injection sites on exposure of the knee; Fig. 6 illustrates  
14 injection sites used in UNI knee surgery.

15 Figure 7 is a table of data resulting from use of the  
16 pain protocol as herein defined, utilizing a standard 18  
17 gauge spinal needle for delivery, during 15 total hip  
18 replacement surgeries. The 15 patients (both male and female,  
19 ranging in age from 46-83 years) all suffered from arthritis  
20 of the hip prior to surgery. These patients suffered little  
21 post-operative pain and required only infrequent  
22 administration of oral pain medications such as Darvocet -100  
23 or Vicodin. Additionally, all 15 patients had a reduction in  
24 length of stay in the hospital and spent no time at

1 rehabilitation facilities.

2       Figure 8 is a table of data resulting from use of the  
3 pain protocol as herein defined, utilizing a standard 18  
4 gauge spinal needle for delivery, during 15 partial knee  
5 replacement surgeries. The 15 patients (both male and female,  
6 ranging in age from 63-81 years) all suffered from arthritis  
7 of the knee prior to surgery. These patients suffered little  
8 post-operative pain and required only infrequent  
9 administration of oral pain medications such as Darvocet -100  
10 or Vicodin. Several patients did not require any pain  
11 medication after partial knee replacement surgery.  
12 Additionally, all 15 patients had a reduction in length of  
13 stay in the hospital and spent no time at rehabilitation  
14 facilities.

15       Figure 9 is a table of data resulting from use of the  
16 pain protocol as herein defined, utilizing a standard 18  
17 gauge spinal needle for delivery, resulting from 15 total  
18 knee replacement surgeries. The 15 patients (both male and  
19 female, ranging in age from 55-82 years) all suffered from  
20 arthritis of the knee prior to surgery. These patients  
21 suffered little post-operative pain and required only  
22 infrequent administration of oral pain medications such as  
23 Darvocet -100 or Vicodin. Additionally, all 15 patients had  
24 a reduction in length of stay in the hospital and spent no

1 time at rehabilitation facilities.

2 As is demonstrated by the data presented herein, the  
3 method of the instant invention can significantly reduce or  
4 eliminate post-operative pain resulting from major  
5 orthopaedic surgery and thus additionally reduce the length  
6 of both recovery and rehabilitation periods for patients.

7 All patents and publications mentioned in this  
8 specification are indicative of the levels of those skilled  
9 in the art to which the invention pertains. All patents and  
10 publications are herein incorporated by reference to the same  
11 extent as if each individual publication was specifically and  
12 individually indicated to be incorporated by reference.

13 It is to be understood that while a certain form of the  
14 invention is illustrated, it is not to be limited to the  
15 specific form or arrangement herein described and shown. It  
16 will be apparent to those skilled in the art that various  
17 changes may be made without departing from the scope of the  
18 invention and the invention is not to be considered limited  
19 to what is shown and described in the specification. One  
20 skilled in the art will readily appreciate that the present  
21 invention is well adapted to carry out the objectives and  
22 obtain the ends and advantages mentioned, as well as those  
23 inherent therein. The various anesthetics, anti-  
24 inflammatories, biologically related compounds, methods,

1 procedures and techniques described herein are presently  
2 representative of the preferred embodiments, are intended to  
3 be exemplary and are not intended as limitations on the  
4 scope. Changes therein and other uses will occur to those  
5 skilled in the art which are encompassed within the spirit of  
6 the invention and are defined by the scope of the appended  
7 claims. Although the invention has been described in  
8 connection with specific preferred embodiments, it should be  
9 understood that the invention as claimed should not be unduly  
10 limited to such specific embodiments. Indeed, various  
11 modifications of the described modes for carrying out the  
12 invention which are obvious to those skilled in the art are  
13 intended to be within the scope of the following claims.